United States Patent [19]

Panetta et al.

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[45] **Date of Patent: Jul. 8, 1986**

[54] **UNIVERSAL MAMMOGRAPHY COMPRESSION SYSTEM**

[76] Inventors: **Patrick Panetta**, 29 Keswick Dr., East Islip, N.Y. 11730; **Jack Wennet**, 20 Spinner La., Commack, N.Y. 11725

[21] Appl. No.: **601,279**

[22] Filed: **Apr. 17, 1984**

[51] **Int. Cl.**[4] **G03B 41/16**

[52] **U.S. Cl.** **378/037; 378/180**

[58] **Field of Search** 378/037, 177, 196, 195, 378/179, 180

[56] **References Cited**

U.S. PATENT DOCUMENTS

3,824,397 7/1974 Bauer et al. 378/37

Primary Examiner—Alfred E. Smith
Assistant Examiner—T. N. Grigsby
Attorney, Agent, or Firm—Lackenbach Siegel Marzullo Presta & Aronson

[57] **ABSTRACT**

A mammography compression system provides for both non-magnification compression examination as well as magnification compression examination through a large plurality of positions whereby the patient may remain seated upright or standing. The system permits utilization of a radiologist's present in place X-ray equipment and readily mounts for juxtaposition with the existing in place x-ray system.

15 Claims, 11 Drawing Figures

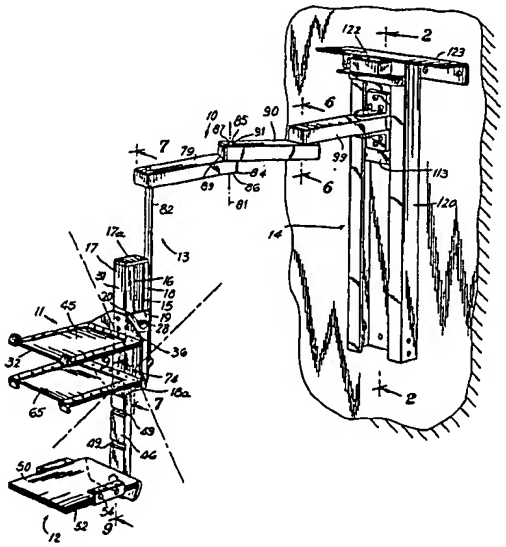

FIG. I

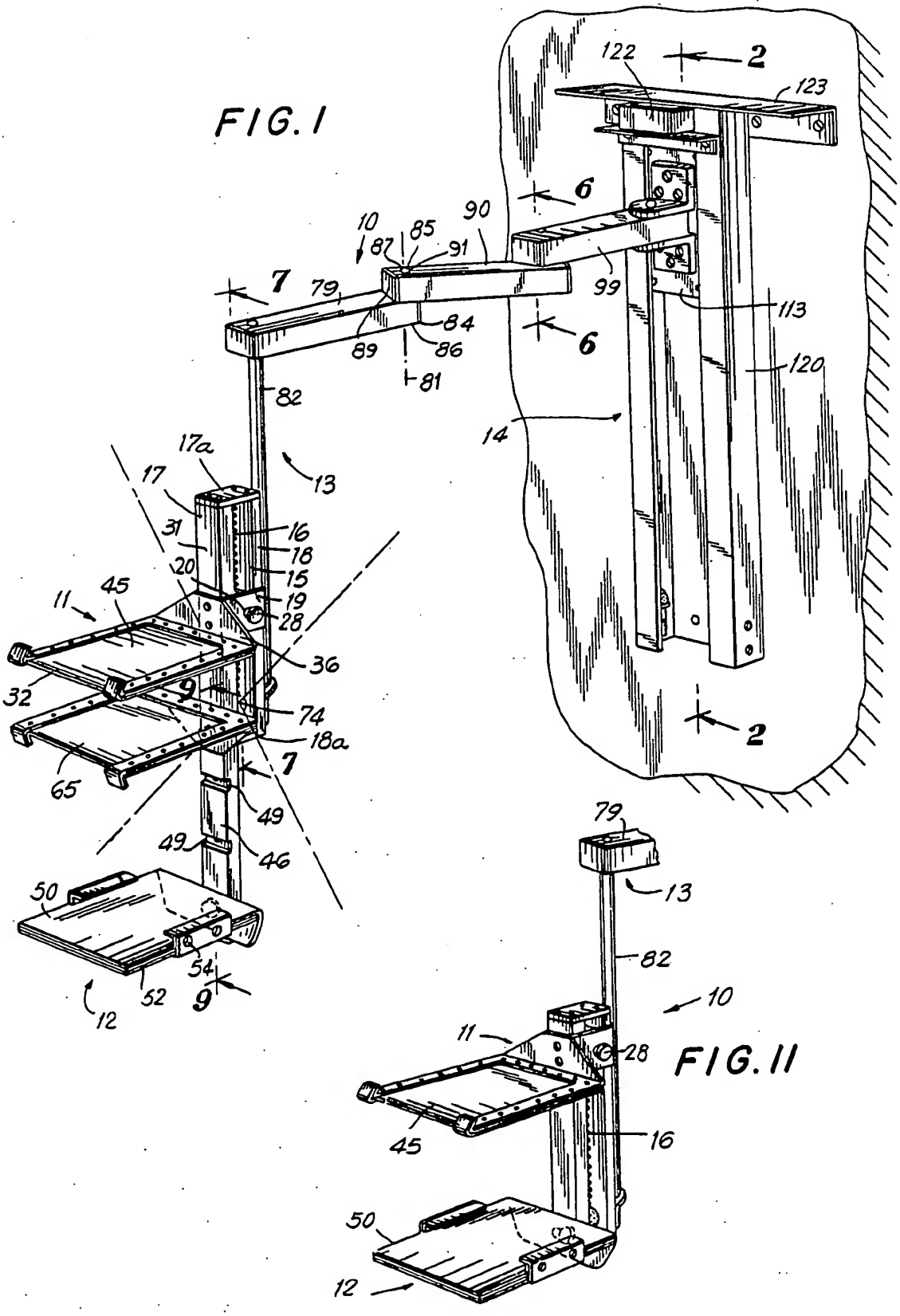
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FIG. II

FIG. 2

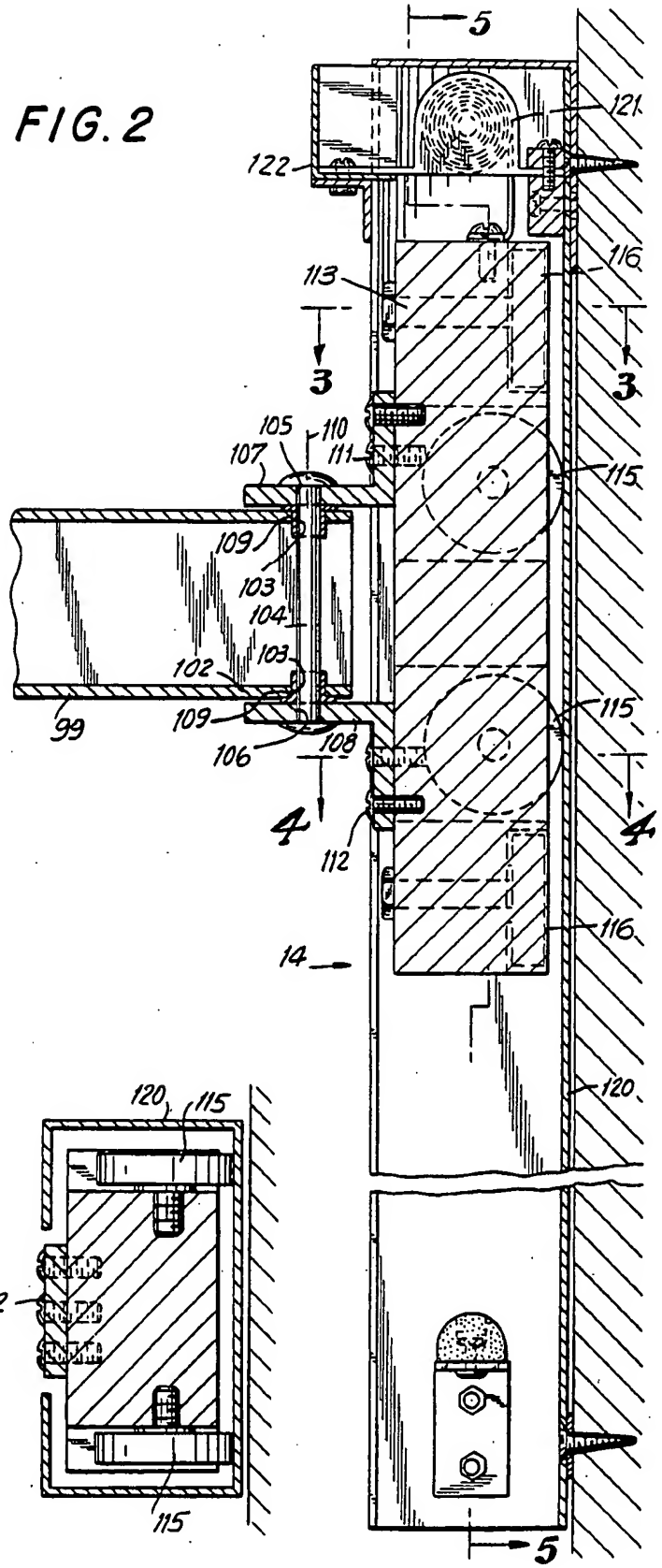

FIG. 3

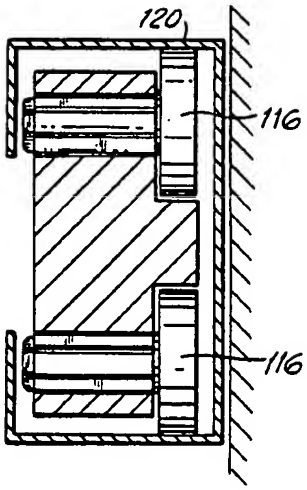

FIG. 4

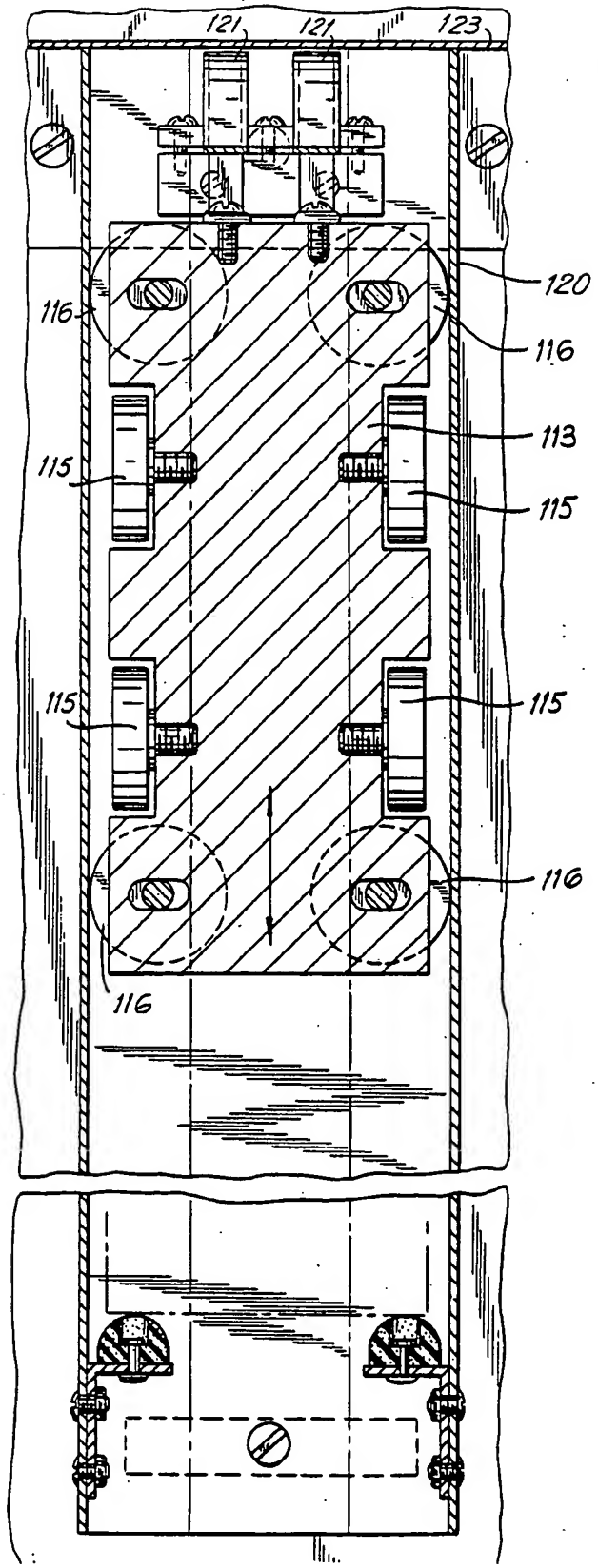
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FIG. 5

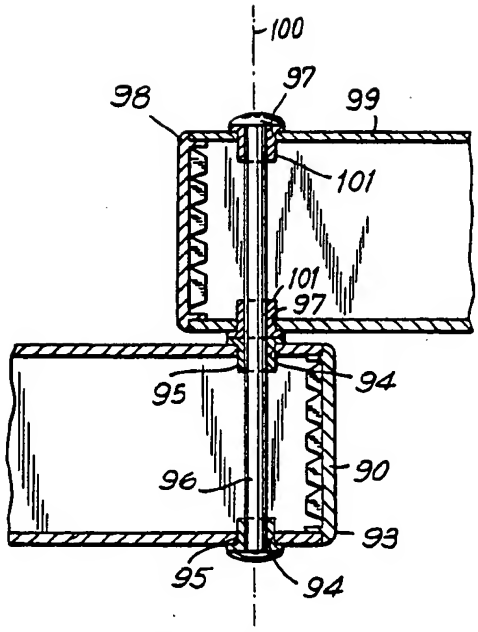
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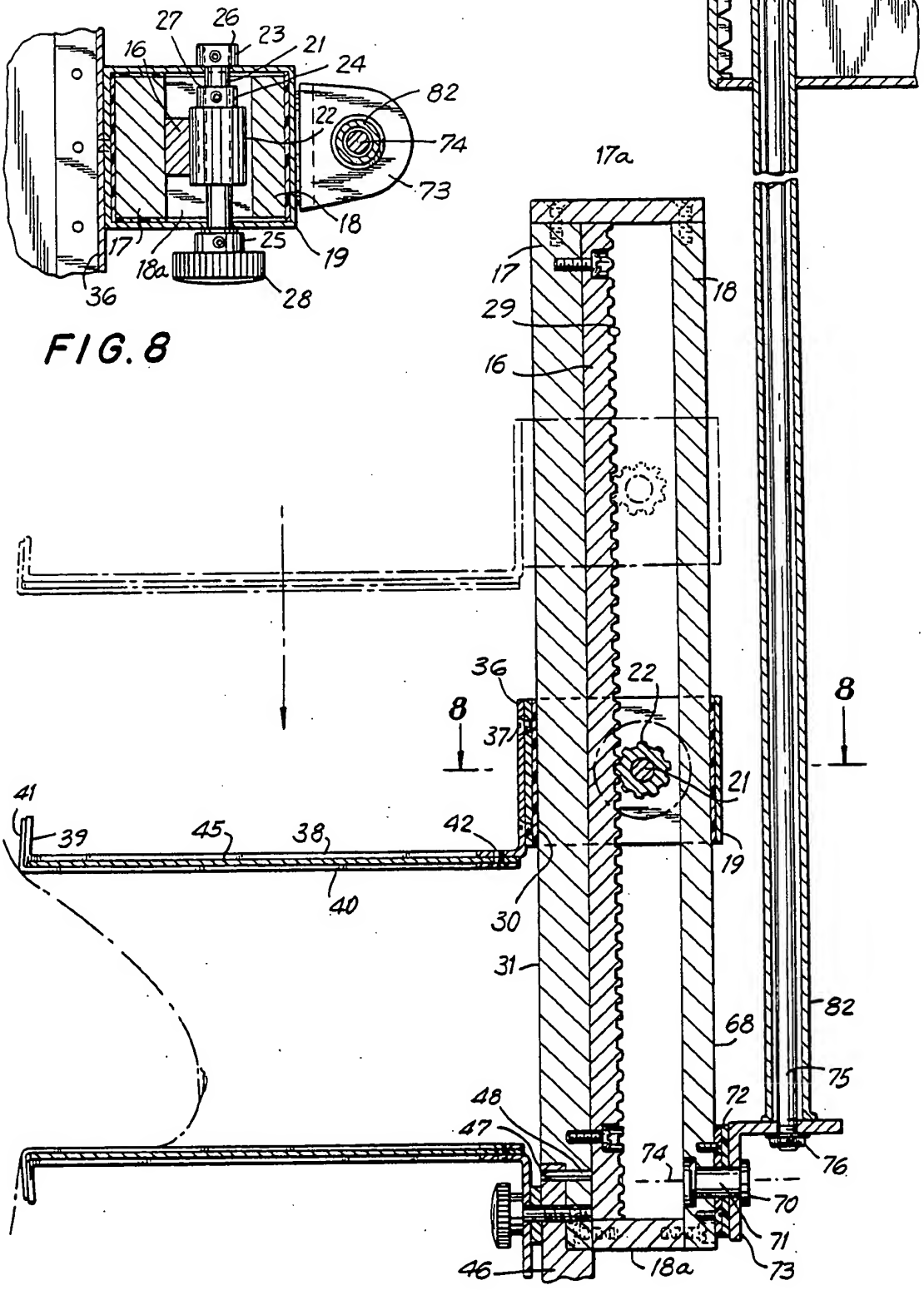
FIG. 6

FIG. 7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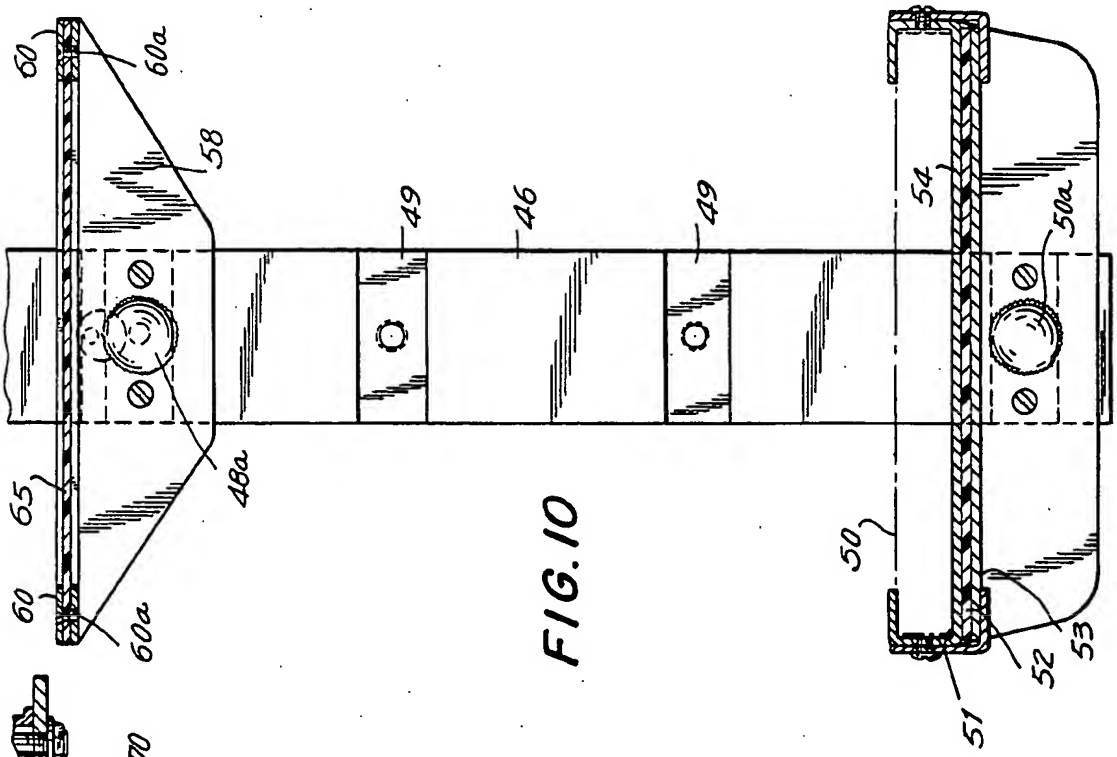
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FIG. 10

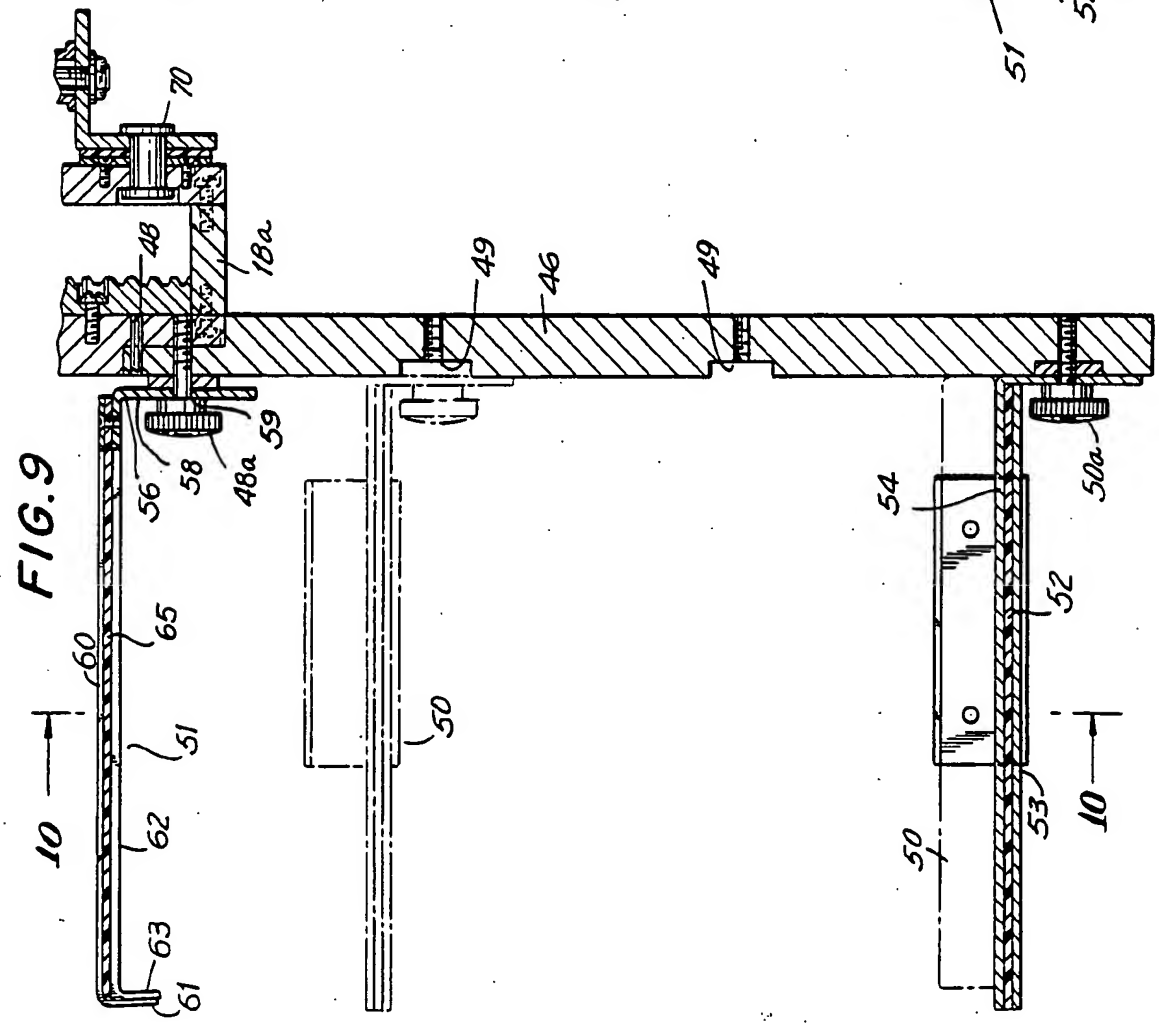
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FIG. 9

UNIVERSAL MAMMOGRAPHY COMPRESSION SYSTEM

FIELD OF THE INVENTION

This invention relates to compression mammography. Specifically, this invention relates to a system for universal positioning for compression mammography.

BACKGROUND AND DISCUSSION OF THE PRIOR ART

In the field of compression mammography, the breast is compressed between plates and the X-ray taken. It is necessary to provide several angular compression positions, as well as providing for degrees of magnification to obtain a thorough examination. Generally, with prior art compression devices, the patient would have to assume diverse, uncomfortable positions in order to obtain this full series of X-rays. Further, the diverse existing in-place mounted X-ray emmission equipment impairs the radiologist or technician in multiply positioning the patient within the relative fixed geometry offered by existing in-place X-ray devices.

Specifically, in Lasky, U.S. Pat. No. 3,578,971, there is disclosed the gravitational suspension of the breast between compression plates, and in Redington et al. U.S. Pat. No. 3,973,126 there is disclosed a supine patient support and pivoting device in conjunction with built-in X-ray unit.

Now there is provided by the present invention a compression mammography system in which a full multi-positioned series of X-ray shots, including magnification shots, is available while the patient remains seated or standing.

SUMMARY OF THE INVENTION

A mammography compression system having breast support and compression elements for magnification and non-magnification X-rays through diverse angular and translation portions so as to accomodate the user in an upright position while utilizing the existing in-place X-ray generator of the radiologist.

DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view of the mammography system of the present invention in the magnification X-ray mode;

FIG. 2 is an enlarged sectional view taken along line 2—2 of FIG. 1;

FIG. 3 is a sectional view taken along line 3—3 of FIG. 2;

FIG. 4 is a sectional view taken along line 4—4 of FIG. 2;

FIG. 5 is an enlarged sectional view taken along line 5—5 of FIG. 2;

FIG. 6 is an enlarged partial sectional view taken along line 6—6 of FIG. 1;

FIG. 7 is an enlarged sectional view taken along line 7 of FIG. 1 showing the action of the compression plates in compressing a breast;

FIG. 8 is a partial sectional view taken along line 8—8 of FIG. 7;

FIG. 9 is an enlarged partial sectional view taken along line 9—9 of FIG. 1;

FIG. 10 is a partial sectional view taken along line 10—10 of FIG. 9; and

FIG. 11 is a partial perspective view of the mammography system of the present invention in the non-magnification X-ray mode.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring to the FIGURES, there is shown the system of the present invention generally referred to as **10**. System **10** in broad terms is formed of a breast examination support section **11**, an X-ray plate mount section **12**, arm mount assembly **13** and a fixed support attachment assembly **14**.

Breast examination support system **11** is formed with central housing **15** having a gear rack **16** vertically mounted therein and held in place between front and back members **17** and **18** and upper and lower crossbars **17***a* and **18***b* respectively. A sleeve **19** is mounted on and slidably disposed with relation to housing **15**. Sleeve **19** is formed with through hole **20** which receives shaft **21** carrying spur gear **22**, bushings **23**, **24** and **25**, set screw collars **26** and **27** and manual compression adjustment knob **28**. Spur gear **22** is sized and aligned to engage teeth **29**. With the turning of knob **28**, gear **22** engages rack **16** so as to cause sliding movement of sleeve **19** relative to housing **15**. A Delrin plastic slide plate **30** is mounted adjacent front wall **31** to facilitate sliding movement of the sleeve relative to the housing.

Upper compression plate assembly **32** is mounted to front wall **31** of sleeve **19** for movement with sleeve **19**. Assembly **32** is formed of compression frame **35** having a rear mounting flange **36** mounted to wall **31** as at **37**, and a pair of outwardly disposed fingers **38** having upwardly bent outward ends **39**. A pair of retainer fingers or strips **40** with upwardly bent ends **41** are connected to fingers **38** through coincident holes mounting elements **42** with a transparent compression plate **45** fixedly held between fingers **38** and strips **40**, for purposes hereafter appearing.

Plate **45** is formed of a polycarbonate, preferrably Lexan, and importantly, is only 0.030-0.040 inches in thickness. Prior art compression plates were undesirably 0.060 to 0.5 inch in thickness.

An elongated positioning bar **46** is formed with an alignment hole **47** for receiving alignment pin **48** at the lower end of housing **15** as well as screw mounting elements **48***a*. A series of vertically spaced holder mount slots **49** are provided in bar **46**. Each slot **49** is sized to removably mount an X-ray plate assembly **50** for magnification shots. X-ray plate assembly **50** is formed of conventional X-ray plate **52**, integrally mounted with a cover **53** and holder **54**. A mounting screw **50***a* holds assembly **50** to bar **46**.

Lower compression plate assembly **51** is mounted (for magnification X-ray) to the alignment pin **48** and through mounting screw **48***a* to the positioning bar **46**. Lower compression plate assembly **51** is formed of compression frame **56** having a rear mounting flange **58** with hole **59** for alignment with screw **48***a*, and a pair of outwardly disposed fingers **60** having downwardly bent outward ends **61**. A pair of retainer strips or fingers **62** formed with downwardly bent ends **63** are connected to fingers **60** through coincident mounting elements **64** with a transparent plastic compression plate **65** fixedly held between fingers **60** and strips **62** by elements **60***a*. Plate **65** may be similarly sized as plate **45**.

For non-magnification X-rays, bar **46** and lower compression plate assembly **51** are removed, and X-ray plate

assembly 50 directly mounted to alignment pin 48 (FIG. 11).

The rear wall 68 of housing 15 is provided with a pivot or rotation assembly 70 having a pivot pin 71 mounted in rotation housing elements 72 and L-flange 73 to provide a pivot axis 74. Section 11 may thereby be pivoted to the desired angle. A vertical rod or cylindrical bar 75 is mounted at one end 26 to flange 73 and the other end 77 to end 78 of first arm 79. End 77 is mounted with jam nut 80 to permit rotation of the bar 75 and in turn breast examination section 11 about the rotation axes of the arms (e.g., axis 81 of the first arm 79). Axis 81 is perpendicular to axis 74. A sleeve 82 is slidably fitted over bar 75 and is sized and formed so as to be held by the patient during examination.

First arm 79 is formed at its rearward end 84 with through hole 85 and bushings 86 for receiving rod 87. Rod 87 in turn passes through hole 88 at the forward end 89 of second arm 90, with bushings 91 completing the assembly for providing pivot axis 81. Second arm 90 is formed at its rearward end 93 with through hole 94 and bushings 95 for receiving rod 96, which rod extends upwardly through hole 97 at the forward end 98 of third arm 99 to provide pivot 100. Bushings 101 complete the assembly. FIG. 6 shows the second and third arm connection which is similar to the first and second arm connection.

The rearward end 102 of third arm 99 is formed with through hole 103 for receiving rod 104. Rod 104 also passes through holes 105 and 106 of opposed L-flanges 107 and 108 respectively. Bushings 109 complete this assembly to provide pivot axis 110. L-flanges 107 and 108 are mounted at 111 and 112 to vertical trolley assembly 113 of attachment assembly 14. Trolley assembly 113 is formed with radial bearings 115 and lateral bearings 116 so as to be slidably received in wall mount C-channel 120. A pair of conventional constant pull spring counterbalances 121 are mounted to the trolley assembly 113 and to the C-channel 120 to provide the trolley with vertical reciprocal travel in the C-channel to any desired height. A spring assembly cover 122 completes the assembly.

Attachment assembly 14 may be wall mounted as shown in FIG. 1, or an attachment bracket 123 provided for ceiling mount.

By the aforesaid manner of construction, the breast examination support unit, for either magnification or non-magnification X-ray may be rotated about axes 74 and 81, as well as 100 and 110 and also being translationally moved through pivot arms or linkages 79, 90 and 99 and raised or lowered through trolley 113, to the desired position for the specifically desired X-ray angle. The patient's breast is then placed between the upper compression plastic plate 45 and either the lower compression plastic plate 65 (magnification) or the X-ray plate assembly (non-magnification) 50 and the upper plate 45 lowered by knob 28 to compress the breast. With the breast compressed, the X-ray technician then aligns the existing X-ray generator with the afore-discussed universal system. All the aforesaid movements and alignments may be accomplished with the patient in an upright seated or standing position. The patient may then extend her arms and grasp sleeve 82 with her hands for ease in taking the X-ray. In using the present system, there is no need for the patient to assume a supine position.

It is to be noted that the several pivot and translation movements of the present system permit the breast examination support section to fully translate a volume of at least more than a quadrant of a cylinder.

It is also noted that the dial knob, spur gear and gear rack assembly permits compression of the breast in a locked position with exertion of counter-forces of the compressed breast on the upper plate.

The system design of the present invention permits utilization of thinner compression plates than heretofore with concommitant improvement in X-ray transmission.

The afore-described universal positioning system permits the patient to remain seated or standing upright during a full series of X-rays.

The invention has been described in detail herein in accord with certain embodiments thereof, yet many modifications and changes therein may be effected by those skilled in the art. Accordingly, it is intended by the appended claims to cover all such modifications and changes as fall within the true spirit and scope of the invention.

What is claimed is:

1. A mammography compression system for a patient comprising; breast examination support means having opposed upper and lower compression plate mounts and compression plates disposed in said mounts, for compressing the breasts of a patient therebetween; said breast examination support means further comprising an X-ray plate mount for mounting an X-ray plate in a plurality of positions relative to said upper compression plate; mounting means connected to said breast support means at an end of the mounting means; attachment means connected to another end of said mounting means for attachment to a fixed support; said mounting means comprising means for retractably and extendably moving said breast support means relative to said fixed support, and means for rotatably moving said breast examination support means; and said compression and X-ray plate mounts being formed so that said X-ray plate is mountable in said lower compression plate mount, whereby said breast examination support means is movable to several examination positions while the patient remains substantially upright, and with the use of said compression plates and said X-ray plate, there is a magnification X-ray and with the upper compression plate and said X-ray plate in the lower compression plate position, there is a non-magnification compression X-ray.

2. The mammography compression system of claim 1, said upper compression plate mount further comprising means to vertically move said mount.

3. The mammography compression system of claim 1, each said plate mount being formed with pairs of spaced, parallel outwardly extending fingers, and wherein the outward ends of the fingers of said upper mount being upwardly bent and the outward ends of said lower mount being downwardly bent.

4. The mammography compression system of claim 1, said X-ray plate mount being formed so as to be detachable from said compression plate mounts.

5. The mammography compression system of claim 1, said X-ray plate mount being an elongated member being formed with a plurality of spaced slots forming said plurality of X-ray plate mount positions.

6. The mammography compression system of claim 1, said mounting means and attachment means being formed so as to provide reciprocal vertical movement to said breast support means.

7. The mammography compression system of claim 6, said movements of said breast support means transversing a spatial volume at least equal to that of about a quadrant of a cylinder.

8. The mammography compression system of claim 1, said compression plates being transparent plastic plates.

9. The mammography compression system of claim 8, each said compression plate being no greater than about 0.040 inch in thickness.

10. The mammography compression system of claim 9, said plates being a polycarbonate.

11. The mammography compression system of claim 1, said means to rotatably move said breast support means comprising a vertical member and means to pivotally mount said breast support means about one axis perpendicular to said vertical member and about a second axis parallel to said vertical member.

12. The mammography compression system of claim 11, said vertical member extending upwardly beyond the breast support means and being formed so as to be gripped by the user during examination.

13. The mammography compression system of claim 11, said means to retractably and extendably move said breast support means comprising a plurality of arm linkages, and pivot means interconnecting said linkages.

14. The mammography compression system of claim 13, said attachment means comprising means to mount the system to a vertical wall and further comprising means to reciprocally vertically move said linkages and in turn said vertical member and breast support means.

15. The mammography compression system of claim 14, further comprising means to stop the vertical movement.

* * * * *

US005971998A

United States Patent [19]

Russell et al.

[11] Patent Number: 5,971,998

[45] Date of Patent: Oct. 26, 1999

[54] SUPPORT DEVICE AND METHOD FOR CONTROLLING BREAST THICKNESS DURING STEREOTACTIC GUIDED NEEDLE BIOPSY

[75] Inventors: **Donald G. Russell**, 86 Windsor Rd., Kensington, Conn. 06037; **Stewart E. Bober**, 3 Pheasant Chase, West Hartford, Conn. 06117

[73] Assignees: **Donald G. Russell**, Kensington; **Stewart E. Bober**, West Hartford, both of Conn.

[21] Appl. No.: **09/052,659**

[22] Filed: **Mar. 31, 1998**

[51] **Int. Cl.**[6] **A61B 19/00**

[52] **U.S. Cl.** **606/130**; 606/1; 606/97; 378/37; 378/208; 604/369

[58] **Field of Search** 606/130, 1, 97; 604/369; 600/231, 227; 5/630, 397, 398, 400; 378/37, 208

[56] **References Cited**

U.S. PATENT DOCUMENTS

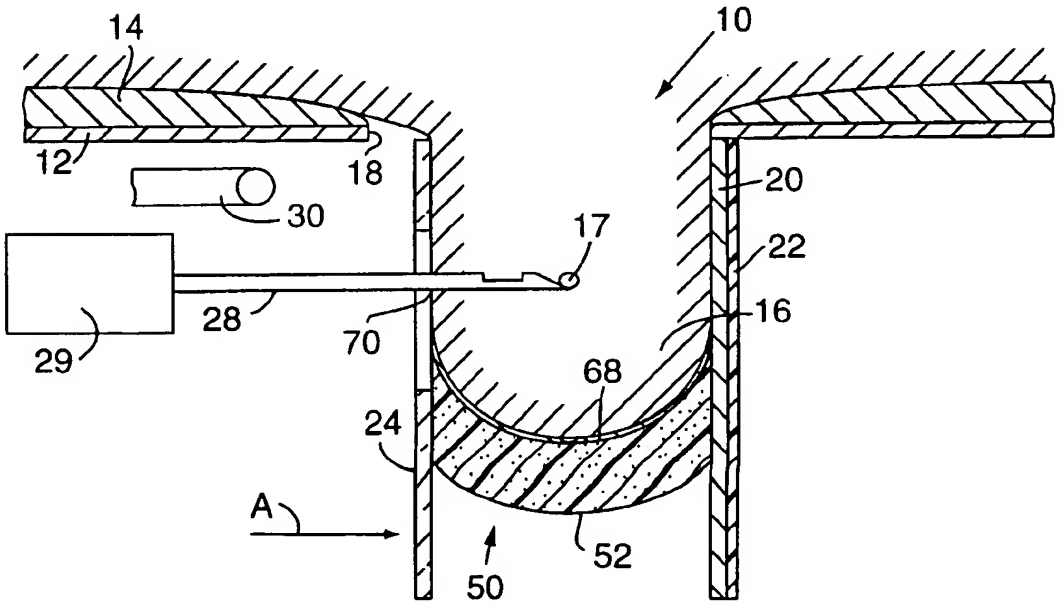
4,691,333	9/1987	Gabriele et al.	378/37
5,507,049	4/1996	Lane	5/484

Primary Examiner—Michael Buiz
Assistant Examiner—Lien Nao
Attorney, Agent, or Firm—Cummings & Lockwood

[57] **ABSTRACT**

A support device for controlling breast thickness during stereotactic guided needle biopsy is provided. The support device includes a compressible support having an inner surface which extends adjacent to a substantial portion of a peripheral surface of a patient's breast when the breast and the support are disposed between the fixed and pressure plates of an apparatus for performing stereotactic guided needle biopsy. The compressible support restricts the inferior and lateral excursion of the breast as the plates are moved toward one another and the patient's breast and the compressible support are pressed between the plates. A method for controlling breast thickness during stereotactic guided needle biopsy is also provided.

20 Claims, 3 Drawing Sheets



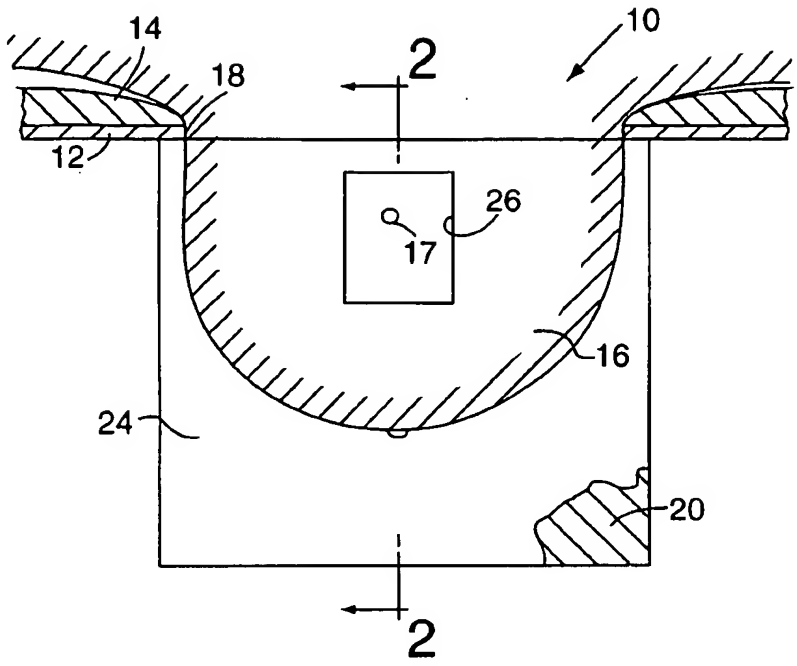


FIG. 1
PRIOR ART

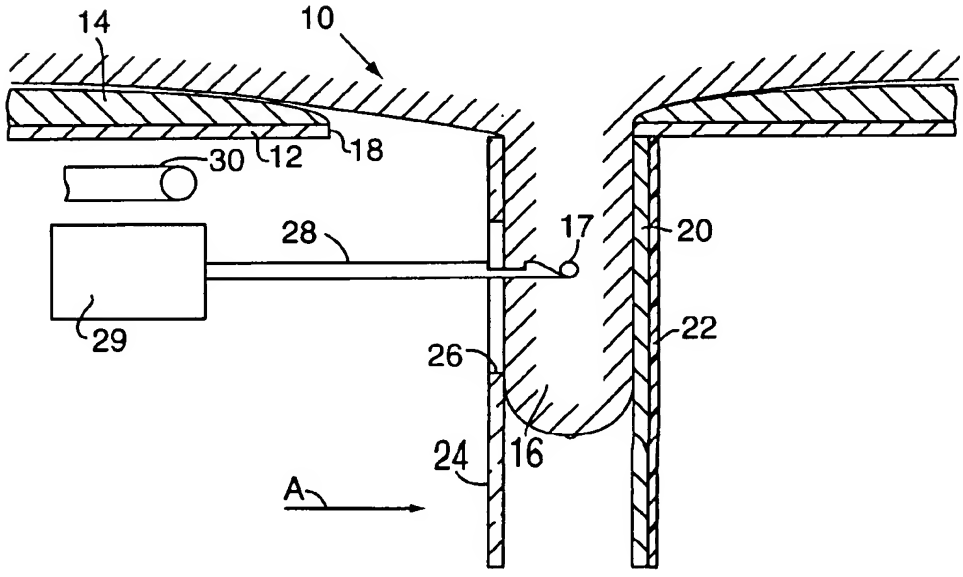


FIG. 2
PRIOR ART

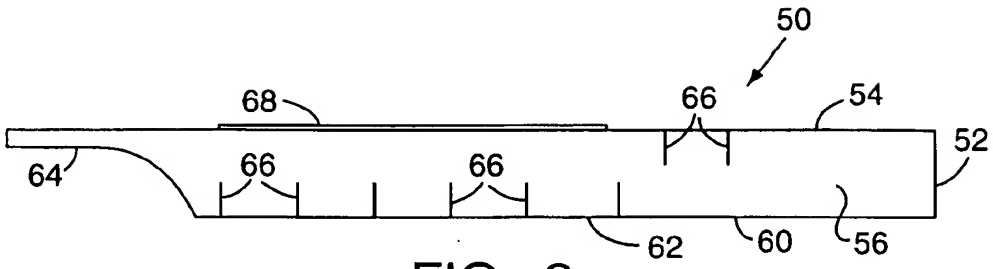


FIG. 3

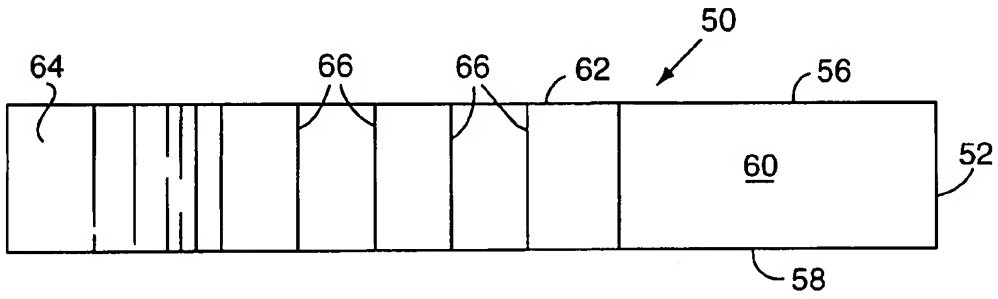


FIG. 4

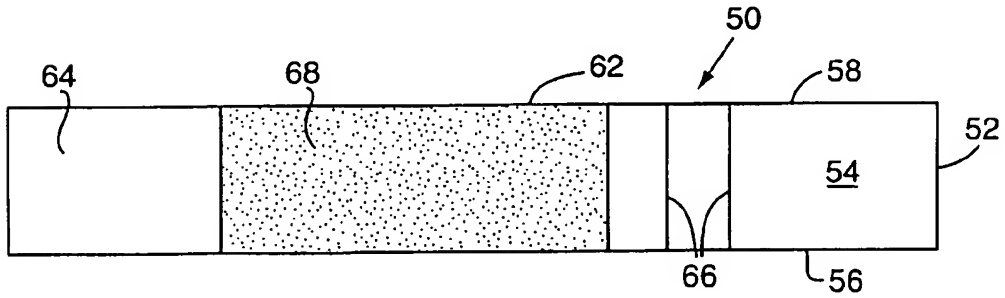


FIG. 5

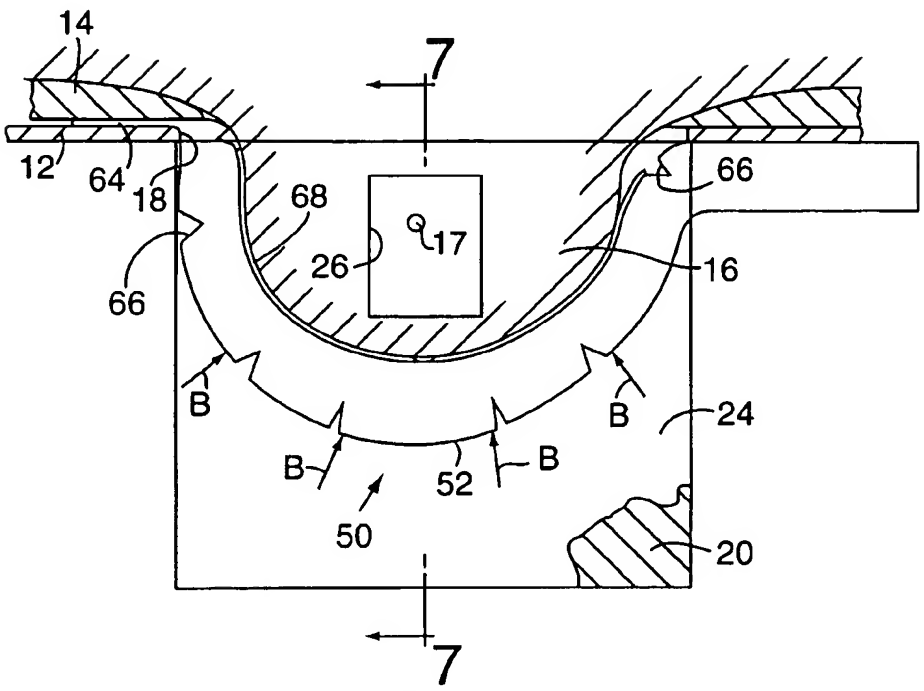

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FIG. 6

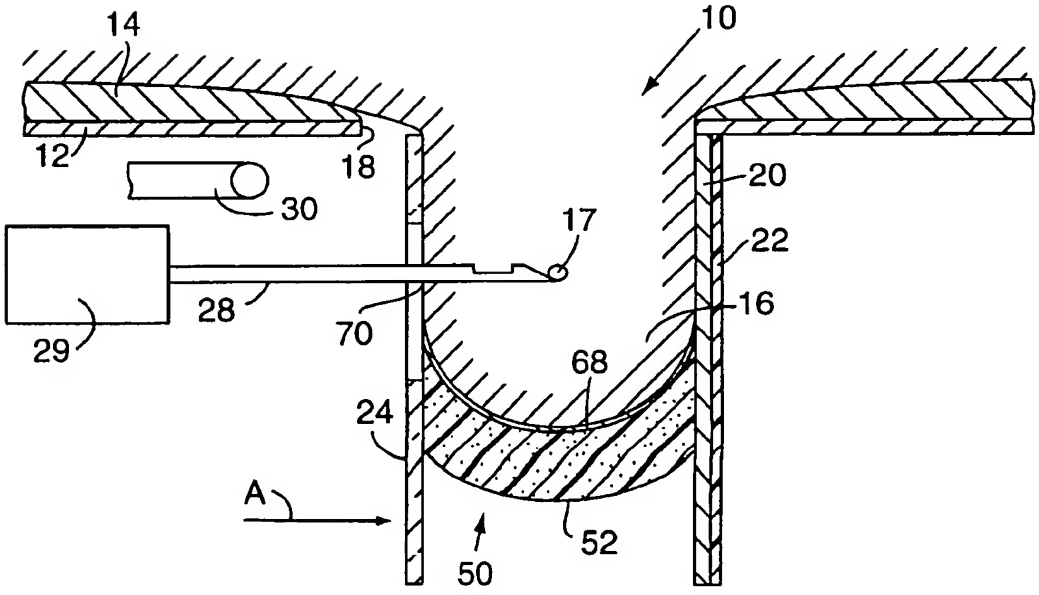
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FIG. 7

SUPPORT DEVICE AND METHOD FOR CONTROLLING BREAST THICKNESS DURING STEREOTACTIC GUIDED NEEDLE BIOPSY

FIELD OF THE INVENTION

This invention concerns a device and a method for controlling the thickness of a patient's breast during the procedure of stereotactic guided needle breast biopsy. More particularly, this invention concerns a support device that is positioned adjacent to a patient's breast to limit the inferior and lateral excursion of the breast tissue as the breast is pressed during needle biopsy, which results in a significant increase in breast thickness.

BACKGROUND OF THE INVENTION

Breast cancer is a leading killer of American women. However, very significant technical improvements in the sensitivity of mammography have been made over the past decade leading to much earlier detection of cancers in many patients. Early diagnosis and treatment results in dramatically improved cure rates. With the improved radiographic resolution which is available in current mammographic studies, radiologists are detecting a greater number of suspicious densities, microcalcifications and other tissue distortions that may represent an early cancer. Biopsy of these suspicious findings is very frequently recommended to determine whether or not the patient has a malignancy.

Customary surgical biopsy is an invasive procedure that requires hospitalization, general anesthesia, a surgical incision and the removal of one or more moderately large tissue specimens to be certain that the area in question is removed. Within the last 5 years, a method of tissue sampling has been developed, wherein a needle or canula is "fired" or injected into and through a suspicious lesion by a spring loaded biopsy device or "gun". In this method, known as stereotactic guided needle biopsy, the sampling needle is guided by preliminary stereotactic radiographs from which the exact location and depth of the lesion is calculated. This information is programmed into the biopsy device so that the sampling needle can be guided to and traverse the area to be sampled. Accuracy of needle placement is plus or minus 2 to 5 mm.

As mentioned above, the sampling needle must pass through the suspicious lesion. The minimum needle "throw" or excursion to obtain a satisfactory core from the lesion is about two centimeters. Since the minimum depth of a lesion to be biopsied in this procedure must be at least 1.0 to 1.5 cm, the actual needle movement is at least 3.5 cm through tissue. For this reason, the breast cannot be reduced in thickness to less than 3.5 cm in order to perform the biopsy by this method.

Newer needles for use in stereotactic guided needle biopsy have a trough about 2.0 cm in length near the tip. When the needle is inserted into a lesion, tissue from the lesion is drawn by suction into the trough and then excised by an inner coring sleeve. Needles of this design are rapidly gaining favor since they provide larger tissue samples which provides more accurate tissue analysis. However, these newer needles must also traverse the length of the tissue to be sampled, and the required amount of breast tissue traversed remains at no less than 3.5 cm.

Known apparatus for performing stereotactic guided needle biopsy is illustrated schematically in FIGS. 1 and 2. The apparatus, generally designated **10**, includes a table **12** which can be elevated. The patient lies face down on a

mattress **14** supported on the table. and the patient's breast **16** containing a lesion to be biopsied, such as the lesion **17**, is suspended through a circular opening **18** approximately 20 cm. in diameter. A fixed, rigid plate **20** is position at one end of the opening **18** adjacent one side of the breast **16**. A radiographic recording mechanism **22**, either mammography film or an electronic digital recording screen, is located behind the fixed plate. On the other side of the breast, there is a movable, mechanically driven, translucent pressure plate **24** with a window opening **26**. A biopsy needle **28**, which is mounted in a spring loaded "gun" or injector **29**, is aligned with the window opening **26**, and a mammography xray tube **30** is positioned proximal to the compression plate.

In practice, the pressure plate is moved toward the fixed plate in the direction indicated by arrow A to moderately press or squeeze the breast between the plates **20** and **24**. After initial radiographic images are taken to identify the lesion **17**, the window **26** is positioned directly over the lesion. Two stereotactic views are then obtained by angling the xray tube 15 degrees to either side of a central line aimed at the lesion. The figures are programmed into the apparatus to determine the depth of the lesion within the breast.

Under sterile conditions and with local skin anesthesia, the biopsy needle **28** is then inserted into the breast just proximal to the target lesion **17**. Accuracy of the needle placement is then assessed by means of another pair of stereo images. If the operator confirms that the area to be biopsied is directly opposite the needle tip, the spring loaded injector then "fires" or injects the needle at a high speed for a distance of about two centimeters so that the needle traverses the length of the lesion. A third set of stereotactic views is then taken. If the needle placement is satisfactory, sampling then proceeds.

As a woman ages, the supportive fibers of the breast lose their elasticity and the fibers elongate. These changes also occur in the skin envelope encompassing the breast. Although there are variations from patient to patient, some breasts become elongated, flaccid, and pendulous. When such a breast is initially pressed between the plates **20** and **24** during the first steps of a stereotactic needle biopsy, the total thickness of the breast can be as little as two centimeters. If the needle is injected in such a case, the 2 cm excursion of the needle will very likely cause the needle to pass through the back side of the breast, impinge on the fixed plate **20**, break or penetrate the plate and impale the patient's breast. Accordingly, in cases where the patient's breast, after it is pressed between the plates **20** and **24**, is too thin for stereotactic biopsy, i.e., the breast does not have a thickness greater than about 3.5 cm, stereotactic needle biopsy must be abandoned and the biopsy performed with a full surgical approach.

Human tissue is not compressible, i.e., there is no reduction in volume when human tissue and, more particularly, breast tissue is pressed or squeezed. Moreover, the skin has a very limited ability to stretch. Accordingly, when a breast is pressed or squeezed there is no change in the total volume of breast tissue. Instead, the tissue is displaced, flattened and altered in shape up to the limits permitted by the supportive fibers of the breast and the confines of the skin envelope.

When the patient's breast is pressed between the fixed plate **20** and the pressure plate **24** as shown in FIG. **2**, the breast generally has the configuration of a half cylinder. The volume, V, of the tissue may be roughly computed by the following mathematical formula:

$$V = \frac{(\pi)(r^2)(h)}{2}$$

Where π is 3.14, r is the radius of the tissue cylinder, and h is the height or thickness of the cylinder.

If the radius r of the patient's breast is reduced, which is accomplished by reducing the area of the breast in contact with the pressure plate, then h or the thickness of the breast must increase in order to reflect the same volume of tissue. This reduction in the breast area in contact with the compression plate may be accomplished by restricting the displacement of the breast interiorly, medially and laterally as it is compressed.

SUMMARY OF THE INVENTION

The present invention provides a support device for controlling the thickness of a patient's breast during stereotactic guided needle biopsy. The device taught by the invention is used in conjunction with an apparatus for performing stereotactic guided needle biopsy of the type having a fixed plate and a pressure plate movable with respect to one another. The device comprises a compressible support having an inner surface which extends adjacent to a substantial portion of a peripheral surface of a patient's breast when the breast and the support are disposed between the fixed plate and the pressure plate of the above-described apparatus. The support controls the thickness of the patient's breast by restricting the inferior and lateral excursion of the breast as the breast and the compressible support are pressed between the plates.

This results in a redistribution of breast tissue characterized by a reduction in the radius of the breast and the surface area of the breast in contact with the plates and a corresponding increase in breast tissue thickness, in accordance with the formula set forth above. Thus, even in patients who would otherwise present a breast thickness of as little as 2 cm when the breast is pressed between the plates, use of the support device results in a redistribution of tissue which provides a breast thickness of at least about 3.5 cm. Accordingly, stereotactic guided needle biopsy can be performed on these patients with a safe, adequate layer of tissue beyond the tip of the injected needle.

In a preferred embodiment, the compressible support is sufficiently resilient so that when the plates are again moved apart to release the pressure on the patient's breast the support assumes it original shape. In a further preferred embodiment, the support device includes a layer of absorbent material disposed between the inner surface of the compressible support and the patient's breast. The layer of absorbent material absorbs and contains blood and other body fluids that may exude from the puncture site of the biopsy needle. In the most preferred embodiment of the invention, the compressible support comprises a flexible foam strip having an inner surface extending adjacent to a substantial portion of a peripheral surface of a patient's breast, and a layer of absorbent material affixed to the inner surface of the foam strip.

A method for controlling the thickness of a patient's breast during stereotactic needle biopsy is also provided.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a front view of a prior art apparatus for performing stereotactic guided needle biopsy with a patient's breast shown disposed between a fixed plate and a pressure plate of the apparatus.

FIG. **2** is a cross section taken along the line **2—2** of the apparatus of FIG. **1** with the patient's breast shown pressed between fixed plate and the pressure plate of the apparatus.

FIG. **3** is a side view of a support device embodying the present invention.

FIG. **4** is a bottom view of the support device shown in FIG. **3**.

FIG. **5** is a top view of the support device shown in FIG. **3**.

FIG. **6** is a front view of the apparatus shown in FIG. **1** with the patient's breast and the support device of FIG. **3** disposed between the fixed plate and the pressure plate of the apparatus.

FIG. **7** is a cross section taken along the line **7—7** of the apparatus shown in FIG. **1** with the patient's breast and the support device of FIG. **3** shown pressed between the fixed plate and the pressure plate of the apparatus.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

FIGS. **3–5** illustrate a support device embodying the present invention. The support device, generally designated **50**, comprises a compressible support or bolster **52** having a top surface **54**, two side surfaces **56, 58** (one shown in FIG. **3**), and a bottom surface **60**. The bolster includes a main support portion **62** and an integrally formed tab portion **64** and is defined by a strip of compressible plastic foam. In the illustrated embodiment, the bolter **52** is formed from a strip of open cell urethane foam.

The overall length of the bolster **52** is variable but is satisfactory for all applications at 18 in. (45 cm), with the tab portion **64** having a length about 6 in. (15 cm). If a bolster of reduced length is required for a particular application, the length may be reduced by simply cutting the strip at any convenient point. The height is approximately 2 in. (5 cm), and the support portion **62** of the bolster has a width of approximately 3 in (7.5 cm). The tab portion **64** has a width of about ⅜ in. (4 mm). A plurality of transverse slits **66, 66** are incised across the top and bottom surfaces of the bolster to a depth of 1 or 2 cm to enhance the flexibility of the foam strip, although it should be understood that this is not necessary in all applications.

As illustrated best in FIG. **5**, a layer **68** of absorbent material is supported on the top surface **54** of the bolster. As explained further below, the layer **68** of absorbent material contains and absorbs blood and other body fluids exuded from the needle puncture site, thus preventing these fluids from contaminating or even damaging the apparatus **10**. The absorbent material comprising the layer **68** may be any sterile absorbent material commonly used in art, and the particular material employed in the illustrated embodiment is non woven methyl cellulose material. The layer **68** of absorbent material may be loosely placed on the top surface **54** of the bolster, or it may be affixed to this surface by, for example, applying adhesive to the bolster or the surface of the layer in contact with the bolster. Since the bolster **52** is intended to be a single use, disposable item, it is preferable to affix the layer **68** to the bolster with adhesive so that both items may be disposed of as a single package.

Referring now to FIGS. **6** and **7** the method of using the bolster **52** in a stereotactic guided needle biopsy procedure will be explained. The patient is placed prone or face down on the mattress **14** supported on the table **12**, and the patient's breast **16** including the lesion **17** to be biopsied is introduced downwardly through the circular opening **18**

formed in the table. As shown in FIG. 6, one end of the bolster 52 is secured to the table 10 by inserting the tab portion 64 between the mattress and the table. The bolster is then swung under the patient's breast and the pressure plate 24 is slowly advanced toward the fixed plate 20 in the direction indicated by arrow A. The foam comprising the bolster 52 compresses as the pressure plate 24 is moved toward the fixed plate 20. Accordingly, the bolster does not in any way hinder or prevent movement of the pressure plate, and once the bolster is pressed between the plates, it is securely but movably held in position between the plates by friction.

While slowly advancing the pressure plate toward the fixed plate, the operator presses upwardly and inwardly on the bolster in the direction indicated by arrows B, B. The bolster is thus manipulated into a cup-like receptacle that extends adjacent to a substantial peripheral portion of the patient's breast, as shown in FIG. 6. As the operator continues to move the pressure plate 24 toward the fixed plate 20 and the patient's breast and the bolster are pressed between the plates, the bolster presses inwardly and upwardly on the patient's breast to restrict the inferior and lateral excursion of the breast. This procedure is continued until the bolster and the patient's breast are in the configuration shown in FIG. 7.

Since, as noted above, breast tissue is not compressible, restriction of the inferior and lateral excursion of the breast by the bolster significantly reduces the radius of the breast and the surface area of the breast in contact with the plates as the bolster and the patient's breast are pressed between the plates. Accordingly, there is a corresponding increase in the thickness of the breast, as compared to the same breast pressed between the plates without the containing pressure applied by the bolster. The increase in breast thickness provided by the bolster is illustrated by comparing the thickness of the patient's breast as shown in FIG. 2 and the thickness of the breast as shown in FIG. 7.

The redistribution of breast tissue achieved with the use of the bolster provides sufficient breast thickness to permit injection of the needle 28 without the danger of the needle completely traversing the breast and impaling the patient's breast to the fixed plate 20. Thus, the present invention enables patients, who would otherwise have to undergo a surgical biopsy, to have breast lesions biopsied by the less invasive procedure of stereotactic needle biopsy. Moreover, since the compressible bolster provides additional support for the breast as the bolster and the patient's breast are pressed between the plates, the force necessary to secure the breast in position is reduced.

Accordingly, the patient experiences much less discomfort during the biopsy procedure, and the risk of tissue damage from prolonged and vigorous pressure which would otherwise have to be applied by the plates is significantly reduced. Still further, since the bolster assists in restricting the movement of the patient's breast between the plates, the risk of inadvertent and undetected repositioning of the breast during the needle biopsy procedure is reduced. This is critical, since such movement of the patient's breast could result in improper needle placement and incorrect tissue sampling.

As described above, a layer 68 of absorbent material is supported on the top surface 54 of the bolster. As shown best in FIG. 7, when the bolster 52 is placed against the patient's breast with the layer 68 of absorbent material immediately adjacent to the breast, the layer 68 extends vertically below the injection site 70 of the needle 28. Accordingly, any blood or other body fluids that exude from the injection site and seep between the pressure plate 24 and the patient's breast will flow by gravity into contact with the absorbent material. The material will contain and absorb these materials, thus preventing them from contaminating and potentially damaging the apparatus 10. Further, the layer of absorbent material reduces the exposure of operating personal to these body fluids.

While the support device of the present invention has been illustrated and described in connection with the preferred embodiment, it should be understood that the invention is not limited in this regard. For example, the bolster 52 is preferably a continuous strip of open cell polyurethane foam. However, other compressible materials, such as other open cell or partially open cell plastic foams, or synthetic or natural rubber are suitable for forming the bolseter. The important factors are that the material be sufficiently compressible so that it does not restrict movement of the plates while being sufficiently rigid to control the configuration of the patient's beast as the bolster and the patient's breast are pressed between the plates. In addition, the material must be sufficiently pliable to permit the bolster to conform to the changing configuration of the patient's breast as it is pressed between the plates, as well as conform to those portions of the biopsy apparatus which are in contact with the bolster.

Further, the support device of the present invention is not limited to the bolster 52 described and illustrated as the preferred embodiment. For example, instead of being provided as a continuous strip of foam, a plurality of discrete foam segments spaced between the plates and adjacent to the patients breast are also suitable. As the foam segments and the patient's breast are pressed between the plates, the foam segments are individually positioned adjacent a corresponding peripheral portion of the patient's breast until the breast is brought into the configuration illustrated in FIG. 7. Of course, each one of the foam segments can be individually provided with a layer of absorbent material supported on the surface of the segment disposed adjacent to the patient's breast.

It should also be understood that while the preferred embodiment of the invention is disclosed in connection with a stereotactic guided needle biopsy apparatus of the type illustrated in FIGS. 1, 2, 6 and 7, the invention is also suitable for use in apparatus having a different construction. For example, apparatus adaptable to standard mammography machines are known wherein the breast to be biopsied is positioned on a horizontal base, and a moveable pressure plate is disposed above and parallel to the base. To perform the biopsy, the pressure plate is lowered onto the breast. In a further modification, the base and the pressure plate are rotable from the horizontal position.

Accordingly, while preferred embodiments have been shown and described, various modifications and substitutions may be made without departing from the spirit and scope of the invention. It is, therefore, to be understood that the present invention has been described by way of example and not by limitation.

What is claimed:

1. An apparatus for performing stereotactic guided needle biopsy comprising a first plate and a second plate moveable with respect to one another and a support device, said support device comprising a compressible support having an inner surface extending adjacent to a substantial portion of a peripheral surface of a patient's breast when the breast and the compressible support are disposed between the first and second plates, said compressible support restricting inferior and lateral excursion of the breast as the first and second

plates are moved toward one another and the patient's breast and the compressible support are pressed between the plates.

2. The support device of claim 1, wherein the compressible support is resilient.

3. The support device of claim 1, wherein the support device further comprises a layer of absorbent material disposed between the inner surface of the compressible support and the peripheral surface of the patient's breast for containing and absorbing blood and other body fluids exuded from a biopsy needle puncture site.

4. The support device of claim 3, wherein the layer of absorbent material is affixed to the inner surface of the compressible support.

5. The support device of claim 4, wherein the layer of absorbent material is removably affixed to the inner surface of the compressible support.

6. The support device of claim 2, wherein the compressible support comprises a flexible foam strip.

7. The support device of claim 2, wherein the compressible support comprises a plurality of discrete flexible foam segments.

8. The support device of claim 6, wherein the foam strip comprises an open cell plastic foam.

9. The support device of claim 1, wherein the support device maintains the patient's breast at a thickness in the range of at least about 35 cm.

10. A method for controlling the thickness of a patient's breast during stereotactic guided needle biopsy, wherein the biopsy is performed with an apparatus having a fixed plate and a pressure plate movable with respect to one another, said method comprising the steps of:

positioning the patient's breast between the fixed plate and the pressure plate;

positioning a compressible support between the fixed plate and the pressure plate and adjacent to a substantial portion of a peripheral surface of the patient's breast;

pressing the patient's breast and the compressible support between the fixed plate and the pressure plate;

and restricting the inferior and lateral excursion of the breast with the support to control the thickness of the patient's breast as the breast and the compressible support are pressed between the plates.

11. The method of claim 10, wherein the compressible support is resilient.

12. The method of claim 10, wherein the support device further comprises a layer of absorbent material disposed between the inner surface of the compressible support and the peripheral surface of the patient's breast for containing and absorbing blood aid other body fluids exuded from a biopsy needle puncture site.

13. The method of claim 12, wherein tile layer of absorbent material is affixed to the inner surface of the compressible support.

14. The method of claim 13, wherein the layer of absorbent material is removably affixed to the inner surface of the compressible support.

15. The method of claim 11, wherein the compressible support comprises a flexible foam strip.

16. The method of claim 11, wherein the compressible support comprises a plurality of discrete foam segments.

17. The method of claim 15, wherein the foam strip comprises an open cell plastic foam.

18. The method of claim 10, wherein the thickness of the patient's breast is controlled to a thickness sufficient to permit injection of a needle without the needle completely traversing the breast as the breast and the compressible support are pressed between the plates.

19. The method of claim 10, wherein the thickness of the patient's breast is controlled to á thickness in the range of at least about 3.5 cm.

20. The method of claim 10, wherein the compressible support at least partially restricts repositioning of the patient's breast during stereotactic guided needle biopsy.

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